

### **Remarks**

Applicant's undersigned attorney thanks Examiner Jiang for her time and helpful comments made during a telephone interview on October 30, 2007. In the interview, the applicability of the rejections made in the office action to the new claims submitted herewith was discussed.

### **Formal Matters**

#### *Information Disclosure Statement*

Applicant requests clarification of whether the Examiner considered the references identified with citation numbers BB and BC on the Information Disclosure Statement submitted August 30, 2005. Because the Examiner both initialed these references as considered and crossed a line through these citations, it is not clear whether Applicant needs to resubmit these references for consideration.

#### *Priority*

The Office Action states that the previously filed claims are not entitled to the benefit of the earlier filed applications to which the instant application claimed priority. Applicants respectfully disagree with the Examiner's allegations that the earlier filed applications do not "disclose a specific and substantial utility" for DCRS9 (now known as interleukin-17 receptor E (IL-17RE)) and do not provide any "guidance or working examples to teach how to use" this protein. However, Applicants do agree with the Examiner that these earlier filed applications do not disclose that IL-17C is a ligand for IL-17RE. Thus, since an antibody that binds to IL-17C and blocks binding of IL-17C to IL-17RE is an element of each of the new claims submitted herewith, Applicant hereby withdraws the priority claim and has amended the specification accordingly.

*Specification*

The Office Action objected to the title of the invention as not descriptive of the elected invention. Applicant respectfully requests reconsideration and withdrawal of this objection in view of the amendment to the title made by the foregoing amendment to the specification.

*Claims*

The Office Action objected to claim 25 as encompassing non-elected subject matter. This rejection is rendered moot by the cancellation of claim 25 by the foregoing amendment to the claims. Applicant respectfully submits that the new claims are directed only to the elected subject matter.

The new claims submitted in the foregoing amendment do not add new matter as they are supported in the specification when combined with what was known in art as of the application filing date. In particular, support for the reference to the extracellular domain of human IL-17RE in new independent claim 33 is found in the specification at least at: p. 16, paragraph [0045], lines 1-4; p. 17, paragraph [0047], last four lines; p. 41, paragraph [0130], lines 4-6; and p. 55, paragraph [0168], lines 1-2. In addition, the phrase "the human IL-17C protein comprises the mature sequence in SEQ ID NO:24" is supported by the specification at p. 33, paragraph [0102] and p. 55, paragraph [0167], lines 1-5, when read in view of Figure 1 on p. 774 of Li et al., PNAS 97(2):773-778 (2000) (Cite No. AN in the Information Disclosure Statement submitted Dec. 29, 2003). Thus, Applicant requests entry of the foregoing amendment to the claims.

**Rejections under 35 USC §112, 2<sup>nd</sup> paragraph**

The Office Action rejected claims 21-26 as indefinite for several reasons, including an allegation the terms IL-17C and IL-17RE are "arbitrary designations that are not well established in the art". Applicant respectfully disagrees with this characterization of the state of the art as of the filing date of the present application. However, in the interest of advancing prosecution, the new claims additionally define the IL-17C and IL-17RE proteins by reference to specific sequences in the Sequence Listing. Applicant respectfully submits that the new claims do not

contain any of the other allegedly indefinite terms cited in the Office Action, and requests reconsideration and withdrawal of the claim rejections under 35 USC §112, 2<sup>nd</sup> paragraph.

**Rejections under 35 USC §112, 1<sup>st</sup> paragraph**

The Office Action rejected claims 21-26 for lack of enablement for the full scope of those claims. Although Applicant does not agree with all the reasons for the lack of enablement rejection, in the interest of advancing prosecution, Applicant has limited the claims to the subject matter that the Office Action states is enabled by the specification: a method of inhibiting IL-17C activity in a subject with psoriasis, using a binding composition that comprises an antigen binding site of an antibody to IL-17C.

The Office Action also rejected claim 23 for lack of adequate written description of a "peptide mimetic of an antibody". This rejection is rendered moot by the foregoing amendment, since claim 23 is cancelled and the new claims 33-35 do not include this term.

For the foregoing reasons, Applicant respectfully requests withdrawal of the rejections under 35 USC §112, 1<sup>st</sup> paragraph.

**Rejections Over Prior Art**

Claims 21-26 were rejected under 35 U.S.C. §102(a) as being anticipated by Chen et al. (US6,569,645). The Office Action states that Chen et al teaches antibodies to IL-17C that inhibit IL-17C and the use of such antibodies for the treatment of psoriasis. Applicant respectfully submits that this rejection can not be maintained because Chen et al do not describe or enable antibodies with all the properties required by the cancelled claims 21-26 and by the present claims 33-36, i.e., antibodies that bind IL-17C and block binding of IL-17C to a particular member of the IL-17 receptor family receptor, IL-17RE.

It is well settled law that an anticipating reference must explicitly or inherently describe all of the elements and limitations of the claim, and must enable one of skill in the field of the invention to make and use the claimed invention. See, e.g., *Merck & Co. v. Teva Pharmaceuticals USA, Inc.*, 68 USPQ2d 185 (Fed. Cir. 2003). Moreover, it is equally well-settled law that a claim limitation is inherent in the prior art only if the limitation is necessarily

present in the prior art, not merely probably or possibly present. See, e.g., *Akamai Technologies, Inc. v. Cable & Wireless Internet Services, Inc.*, 68 USPQ2d 1186 (Fed. Cir. 2003).

While the Chen et al. reference generically describes antibodies that bind to IL-17C, this reference does not describe any such antibodies that were actually made. Moreover, since Chen et al. do not teach binding of IL-17C to any receptor, this reference certainly does not explicitly describe antibodies that block binding of IL-17C to IL-17RE. Thus, while Chen et al may describe and enable antibodies that bind to IL-17C, this reference does not explicitly describe and can not enable the skilled artisan to make antibodies that both bind to IL-17C and block binding of IL-17C to IL-17RE.

During the phone interview, the Examiner suggested that the latter property would be inherently present in antibodies that bind to IL-17C or at least inherently present in inhibitory antibodies that bind to IL-17C. However, it is well known in the art that antibodies that bind to a ligand do not necessarily antagonize the ligand, e.g., do not block binding of the ligand to its receptor. Indeed, it has been the experience of the Assignee of the present application that many antibodies made against cytokines are not antagonizing antibodies. Thus, a generic disclosure of how to make antibodies against IL-17C can not inherently anticipate antibodies that have the required property of blocking binding of IL-17C to IL-17RE. Moreover, this property would only be inherent in inhibitory antibodies to IL-17C if IL-17RE was the only receptor that mediated the signaling of IL-17C. However, the art suggests otherwise.

For example, US2006/0142192 A1 (Example 33, 2<sup>nd</sup> paragraph) teaches that IL-17C binds to IL-17R (also known as IL-17RA) as well as IL-17RE (ZcytoR21). Also, R&D Systems, which sells a recombinant human IL-17C preparation, reports that this preparation binds to an immobilized recombinant IL-17RB/Fc (see the enclosed R&D Systems Specifications and Use Sheet). Because of these reports that IL-17C binds to other members of the IL-17 receptor family, the skilled artisan can not be certain that IL-17C signaling is mediated only by IL-17RE. Indeed, IL-17A has been reported to signal through both IL-17RA and IL-17RC (see US2007/0249533 A1). Thus, since there is at least a possibility that at least some antibodies that inhibit IL-17C activity could do so by binding to a receptor other than IL-17RE, the skilled artisan can not be certain that every inhibitory antibody to IL-17C would block binding of IL-

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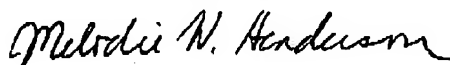
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17C to IL-17RE. In conclusion, since a required property of the antibodies that are used in the claimed method is not necessarily present in the inhibitory antibodies generically described in Chen et al., this reference does not inherently anticipate the present claims.

For the foregoing reasons, because Chen et al do not explicitly or inherently describe antibodies that block binding of IL-17C to IL-17RE and do not enable making such antibodies, the anticipation rejection under 102(a) should be withdrawn.

Applicant respectfully submits that the claims are in condition for allowance. If the undersigned can be of any assistance to the Examiner in addressing issues to advance the application to allowance, please contact Applicant's attorney at the number set forth below.

Respectfully submitted,



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